

REMARKS/ARGUMENTS

Claims 1, 2, 5 – 6, 8 – 13, and 15 - 22 are in the application. Reconsideration is respectfully requested.

Terminal Disclaimer

Filed herewith is a terminal disclaimer for the purpose of overcoming the obviousness-type double patenting rejection of claims 1 - 18 that is specified on page 2 of the Detailed Action.

Claim Rejections Under 35 USC § 102/103

Claims 1, 5 – 6, 11, 13 – 15 and 18 were rejected under 35 USC §§ 102(b) and 103(a), respectively, as anticipated by or rendered obvious by the Smith & Nephew Richards Disposable Cuff document (3 pages, November, 1994), hereafter referred to as SMITH & NEPHEW.

In response, applicant offers the following remarks.

Independent claims 1, 6, 13, and 15

Claim 1

This claim has been amended to change the claim into a method for matching components of an apparatus that includes a tourniquet cuff component and a limb protection sleeve component. The length of the cuff component is selected to be between a predetermined minimum and maximum limb circumference.

The provided sleeve component (which is applied between the cuff and the limb) is formed to apply a pressure between a predetermined minimum pressure and a predetermined maximum pressure.

The method of amended claim 1 concludes with the step of matching the cuff and sleeve components by marking the cuff and sleeve to indicate that those two components match one another.

The method of amended claim 1 is analogous to the apparatus defined in claims 6, and 15 and is believed to be patentable for the reasons set forth next in connection with those apparatus claims.

Claims 6 and 15

Claim 6 has been amended to specify that the means for matching the sleeve to the first indicium that is on the cuff include a second indicium that is on the sleeve.

The present application explains in detail how a certain size of sleeve is selected for use with a cuff that is itself sized for use with limbs of a particular circumferential range. In short, the sleeve is selected to ensure that it is stretched when applied to a limb (underlying a cuff) that has a circumference at the low end of the limb-circumference range. This stretching eliminates wrinkles in the sleeve.

Also, when the sleeve is applied to a limb this is on the high end of the limb-circumference range, the pressure applied to the limb by the stretchable sleeve is low enough¹ to prevent interference with blood flow in the limb. This second criteria for a properly sized sleeve is important, but not mentioned in the prior art of record.

In rejecting claim 6, the Office action applies SMITH & NEPHEW and asserts (page 4) that what is described there inherently includes some indicia *“(such as a label, a mark, an alphabet code, a color code ...)”* on the cuff and stockinette sleeve *“to help a physician select a right pair of cuff and stockinette sleeve for a patient.”*

In response, applicant respectfully traverses the rationale set forth in the Office action for asserting that the claimed matching indicia on both the sleeve and the cuff is an inherent part of SMITH & NEPHEW. SMITH & NEPHEW apparently packs together a cuff and a sleeve, and the associated guidelines warn the user to avoid any wrinkles in the sleeve. There is no rationale however, for reading that reference to include marking on the sleeve that match marking on the cuff. Applicant submits, therefore, that a proper inherency-based rejection has not been made as is required in the Manual of Patent Examining Procedure (MPEP), such as set forth in § 2112, a pertinent portion of which is quoted here:

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

¹ For example, less than 25 mmHg

As mentioned above, these claims were also rejected (in the alternative) as being obvious in view of SMITH & NEPHEW. In particular, the Office action concluded that it would be obvious for one of ordinary skill to mark or label a sleeve to match an associated cuff *“to help a physician or a user to identify the right pair of cuff and sleeve for a patient.”*

In reply applicant notes that there is nothing in the SMITH & NEPHEW reference that suggests this marking. In this regard, applicant points out that apart from apparently recognizing that sleeve wrinkles are undesirable, there is nothing in SMITH & NEPHEW that suggests the necessity of ensuring that an otherwise wrinkle-free sleeve is not too tight (that is, applying a pressure of, for example, more than 25 mmHg, which could lead to injury).

It is applicant's solution to this potential over-pressure problem that leads to the claimed marking of a sleeve to match a cuff. Put another way, an unmarked sleeve may readily avoid the wrinkling problem of concern in SMITH & NEPHEW, but two different wrinkle-free sleeves may apply two different pressures to a limb (one of which pressures may be injuriously high). Thus, each of the claimed sleeves requires a specific marking to ensure it is matched with a cuff that is used with a limb that is within a predetermined limb-circumference range, thereby ensuring that the limb will not be overpressurized by the matching sleeve.

Since SMITH & NEPHEW does not concern itself with the tight-sleeve-pressure problem addressed in the present application, there is no suggestion or motivation there to match and mark the cuffs and sleeves to avoid applying too much pressure to the limb. SMITH & NEPHEW packages a sleeve with each cuff and asks the user to avoid wrinkles. There is nothing in the art of record to suggest that SMITH & NEPHEW be modified to also incorporate a marked sleeve that matches a similarly marked cuff.

As noted in the MPEP, a *prima facie* case of obviousness first requires that the prior art suggest the desirability of the claimed invention:

“To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings....” MPEP §2143

In the case at hand, there is nothing in the prior art that would suggest modifying SMITH & NEPHEW to include sleeves that are marked to match cuffs as presently claimed. Accordingly,

applicant submits that a proper case of *prima facie* obviousness has not been made, and the rejections should be withdrawn.

Claim 13

Claim 13 was rejected under that same grounds applied in rejecting claims 6 and 15. Claim 13, however, calls for providing a visual indication of the size correspondence between the cuff and sleeve. Accordingly, claim 13 is believed to be allowable for the reasons set forth above in connection with claims 6 and 15 since the cited art does not teach or suggest the provision of such a visual indication of size correspondence.

Moreover, claim 13 also points out that the sleeve has a width that is greater than the width of the cuff, thereby to enable part of the sleeve to completely underlie the cuff while another part of the sleeve is folded over the cuff. The Office action does not point out where in the art of record the particulars of this sleeve sizing is taught or suggested. Accordingly, applicant submits that lack of teaching or suggestion in the prior art is another basis for the patentability of claim 13.

Dependent Claims 2, 5, 8 – 12, 16, 17, and 19 - 22

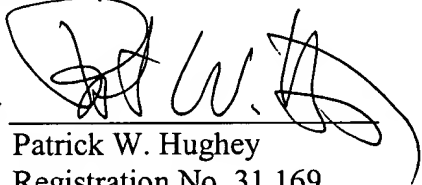
These claims are believed to be patentable in combination their allowable base claims.

Conclusion

In view of the foregoing, applicant believes that all of the currently pending claims are in condition for allowance, and an early notification to that effect is respectfully requested. If the Examiner has any questions, he is invited to contact applicant's attorney at the below-listed telephone number.

Respectfully submitted,
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